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ECCENTRICITY OF THE AORTIC ANNULUS IS NOT ASSOCIATED WITH FUNCTIONAL IMPAIRMENT OF THE TRANSAPICAL JENAVALVE IN AN IN VITRO HYDRODYNAMIC TEST MODEL

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Background: CT analyses of patients with severe aortic stenosis reveal that in the majority of patients, the aortic annulus is not circular, but displays a certain degree of eccentricity. All currently available percutaneous heart valve prostheses are circular in shape. The aim of this study was to assess the performance of the transapical JenaValve® in an in vitro hydrodynamic test comparing circular and eccentric aortic annulus geometry.
Methods: Based on CT data from 123 TAVI patients, a mean annulus eccentricity (eccentricity=short diameter/long diameter) of 0.84 was determined. Two models of aortic roots with valve leaflets, one circular in shape and one displaying an eccentricity of 0.84 were created based on the Reul model. The molds for the models were 3D-printed and cast from silicone. Valve hydrodynamics were evaluated in the CVE pulse duplicator by analyzing high speed video recordings of leaflet motion, flow and pressure data. Measurements were performed 5l/min cardiac output, 80, 100 and 120 mmHg of mean aortic pressure and 120, 70 and 110 BPM, respectively. Experiments were repeated in a cross-over design.
Results: The Analysis was performed with transapical JenaValve prostheses implanted in a circular annulus (n=3) or an annulus with 0.84 eccentricity (n=3). Hydrodynamic testing under both conditions showed good results without significant difference in performance. In the circular model the JenaValve showed an average regurgitation volume (RV) of 3.49ccm±0.12ccm corresponding 4.69%±0.20% of the total stroke volume (SV). An increase of RV to 3.57ccm±1.61ccm corresponding 4.81%±2.05% of the total SV was seen in the oval annulus, representing only a small increase. Cross-over hydrodynamic testing showed similar results.
Conclusions: This is the first experimental in vitro study demonstrating no significant difference in valve performance with regard to regurgitation volume for a commercially available percutaneous valve whilst implanted in a circular and eccentric annulus. This may be due to the slim and flexible valve stent design, the use of a native porcine root valve as opposed to single pericardial leaflets and the clipping mechanism of the transapical JenaValve.

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Atrial Fibrillation, Stroke and Mortality in TAVI

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Background: Transcatheter Aortic Valve Implantation (TAVI) has become a reasonable approach for patients with severe symptomatic aortic stenosis (AS) and high operative risk. This approach may be hampered by high occurrence of stroke during and after the procedure. With the association of atrial fibrillation (AF) and CVA well documented, the objective of the present report was to evaluate the effect of pre-procedural and new onset atrial fibrillation (NOAF) on mortality and stroke outcomes in patients undergoing TAVI.
Methods: We analyzed the data on 380 consecutive elective patients undergoing TAVI between September 2008 and April 2013 in our interventional cardiology department. Post-procedural AF was defined as new onset AF occurring within 30 days of the index procedure. Follow up time was defined as the time from the procedure to an adverse outcome, either mortality of stroke.
Results: The mean follow-up time was 583 and 528 days for the outcome of CVA and mortality respectively. For the total duration of follow-up, CVA and mortality occurred in 19 (10%) and 68 (17.9%) patients respectively. At 30 days follow-up, NOAF occurred in 31 (8.2%) cases and was not associated with higher rate of CVA (0.4% vs. 3.2% of NOAF, p=0.093, p=0.36 in a multivariate analysis after adjustment) or mortality (2.2% vs. 3.2%, p=0.71). At 12-month follow-up no difference in CVA rate or mortality was observed between groups. In contrast, patients with background diagnosis of AF had an increased rate of CVA at 12 months follow-up (1.5% vs. 6.8%, p=0.007, p=0.014 after adjustment for confounding risk factors for CVA) and increased mortality (6.1% vs. 25.4%, p<0.001). The increased rate of CVA and mortality was not driven by difference in baseline characteristics or risk factors for CVA. CHA2DS2VASc score was similar in both groups (4.62±1.1 vs. 4.77±1.08, p=0.246).
Conclusions: The present data suggest that new onset atrial fibrillation in the first 30 days after TAVI does not increase significantly stroke or mortality rate at 30 days and 1 year follow up. Importantly, prior diagnosis of AF significantly increases the rate of stroke and mortality, regardless of known risk factors and baseline characteristics.

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The Annulus Dimension is Crucial to Achieved Good Results in Pure Severe Native Aortic Regurgitation Treated by Transcatheter Aortic Valve Implantation

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Background: Transcatheter aortic valve replacement (TAVR) represent an "off label" option to treat pure severe native aortic regurgitation (SAR) in patients unsuitable for surgical aortic valve replacement due to their high surgical risk. We hereby report the 12 month follow-up of 12 cases of inoperable SAR treated in our Institute using Medtronic CoreValve prosthesis.
Methods: Aortic valve sizing was assessed on 3 dimensional-CT scan and TEE considering perimeter, area, major and minor orthogonal annular diameter. In all cases an oversizing prosthesis (20%) with respect of annular perimeter was used. Predilation with balloon valvuloplasty was never performed. During valve deployment a rapid (180 bpm) pacing was used in order to prevent valve ejection. Twelve patients underwent TAVR with CoreValve prosthesis (mean age 83+4, 7; mean L-Euroscore 31%; male 60%).
Results: In 9 patients a procedural success has been reached using a single valve (n. 3 CoreValve 26 mm; n. 3 CoreValve 29 mm; n. 3 CoreValve 31 mm. Mean annulus size 24,7+ 2 mm) without major complications (no peri-procedural stroke or major bleeding). A new permanent PM implantation was necessary in 3 pts. Post procedure aortic regurgitation grade < 1 was present in 8 patients. In one case a second valve deployment (CoreValve 29 mm in Core-Valve 31 mm) was necessary to reduce the peri-leak severe aortic regurgitation obtaining a final moderate grade of aortic regurgitation. In 2 cases conversion to emergency open surgery and aortic valve replacement was required due to residual severe aortic regurgitation despite a second valve deployment (valve-in-valve). In these patients the large native annulus dimension (mean perimeter of 93+2 mm; mean area of 831+3 mm2) did not permit to use an oversizing device and the CoreVale 31 mm was borderline. In all cases at 6- and 12-month follow up we observed an improved functional capacity (NYHA class I-II post TAVR from NYHA IV pre TAVR was present in9 patients) and no death.
Conclusions: We hypotized that when an oversize prosthesis is used treating SAR by TAVR acceptable results can be achieved. On the contrary very large native annulus dimension should be considered a contraindication to TAVR in SAR

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Post TAVR hypertension is associated with favorable outcome

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Background: TAVI is an emerging therapy for aortic stenosis (AS) patients at high surgical risk. The acute hemodynamic sequelae of this procedure and their clinical relevance are yet unclear.
Methods: Consecutive patients who underwent TAVI in a single center were prospectively monitored for BP response during 5 post-procedural days. Clinical parameters, adverse events and medical treatment were recorded during hospitalization, at 30 days and at 12 months after the procedure. Patients were divided according to their post-procedural BP response into two groups: increased BP and stable BP.
Results: One hundred and five patients were analyzed. Overall, systolic BP increased immediately after TAVI in the entire cohort by an average of 15±31 mmHg. This rise was sustained and led to intensification of anti-hypertensive treatment in 53 patients (51%), these patients were designated as the increased BP group. The increase in systolic BP after TAVI was associated with an increase in stroke volume and cardiac output and was not related to age, baseline cardiac function or procedural outcomes. Patients with increased BP after TAVI had a significantly better prognosis with less adverse events in hospital (21% vs. 62%, p<0.01), after 30 days (30% vs. 71%, p<0.01) and after 12 months (53% vs. 83%, p<0.01) as compared with patients with stable BP.
Conclusions: After TAVI, a substantial number of patients have a significant rise in systolic BP necessitating long term treatment. This increase in BP is associated with an increase in cardiac output and predicts a better clinical outcome.